

AMENDED IN ASSEMBLY JANUARY 5, 2004

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

Assembly Joint Resolution

No. 41

Introduced by Assembly Member Yee

June 19, 2003

Assembly Joint Resolution No. 41—Relative to psychotropic drugs and youth.

LEGISLATIVE COUNSEL'S DIGEST

AJR 41, as amended, Yee. Psychotropic drugs and youth: *the federal Pediatric Research Equity Act of 2003*.

~~This measure would request the President and the Congress of the United States to urge the Food and Drug Administration to probe the reasons for the rise in the use of psychotropic drugs to manage mental health problems in youth and to develop expanded clinical trials and other research regarding the appropriate use of medication in the psychiatric treatment of children and adolescents.~~

This measure would commend the Congress and the President of the United States for recognizing the importance of testing the safety and effectiveness of drugs for pediatric use through the enactment of the Pediatric Research Equity Act of 2003.

Fiscal committee: no.

- 1 ~~WHEREAS, An estimated six million children in the United~~
- 2 *WHEREAS, Federal legislation, known as the Pediatric*
- 3 *Research Equity Act of 2003 (S 650), was introduced in the Senate*
- 4 *of the United States on March 18, 2003, passed by Congress in*
- 5 *July, 2003, and signed by the President on December 3, 2003; and*

1 WHEREAS, The purpose of the Pediatric Research Equity Act
2 of 2003 is to provide the Food and Drug Administration (FDA)
3 with clear authority to require pediatric studies of drugs to ensure
4 their safe and effective use for children and the act applies to all
5 medications whose intended use in pediatrics is the same as adults,
6 thus ensuring complete information about the effects of the drug
7 on children; and

8 WHEREAS, The Pediatric Research Equity Act is landmark
9 legislation that gives the FDA the full authority to require drug
10 manufacturers to test new medicines in children and the full power
11 to order testing of older drugs, including psychiatric medications,
12 that are widely prescribed to children if companies do not conduct
13 studies voluntarily; and

14 WHEREAS, The Pediatric Research Equity Act will provide
15 child and adolescent psychiatrists with safety and efficacy
16 information about medications they prescribe for children and
17 adolescents with mental illnesses; and

18 WHEREAS, There are an estimated six million children in the
19 United States between the ages of six and 18 years of age taking
20 psychotropic drugs, including stimulants such as Ritalin,
21 antidepressants such as Paxil, Prozac, or Zoloft, and
22 amphetamines such as Dexedrine; and

23 WHEREAS, The Pediatric Research Equity Act is timely
24 legislation, especially in light of a recent study published in the
25 Archives of Pediatrics and Adolescent Medicine that identified a
26 rapid increase in the proportion of children and adolescents in the
27 United States taking all types of psychiatric medications from the
28 mid-1980s to the mid-1990s and that spotlighted the relative lack
29 of knowledge about the unknown long-term effects of these
30 medications on the pediatric and adolescent population; and

31 WHEREAS, The Pediatric Research Equity Act will prompt the
32 development of a solid body of long-term research and testing that
33 is needed to determine the long-term safety of psychiatric
34 medications in light of earlier ages of initiation and longer
35 duration of treatment and that is needed to examine drug
36 concentrations in body fluids and tissues over time in children and
37 adolescents to determine the appropriate dosage and frequency for
38 youth of different ages and body sizes; and

39 WHEREAS, Prior to the enactment of the Pediatric Research
40 Equity Act and, as cited in the landmark 2000 Report of the U.S.



1 *Surgeon General on Mental Health, physicians, specifically child*
2 *and adolescent psychiatrists, relied on data from studies in adults,*
3 *any clinical or anecdotal reports of use in child and adolescent*
4 *patients, studies conducted outside the United States, and the*
5 *experience of colleagues when making decisions to prescribe*
6 *drugs, including psychotropic medications, to the pediatric and*
7 *adolescent population; and*

8 *WHEREAS, When prescribed appropriately by a psychiatrist,*
9 *preferably a child and adolescent psychiatrist, taken as*
10 *prescribed, and used in conjunction with a comprehensive*
11 *treatment plan that includes psychotherapy, medication may*
12 *reduce or eliminate symptoms and improve the daily functioning*
13 *of children and adolescents diagnosed with psychiatric disorders,*
14 *and*

15 *WHEREAS, The Pediatric Research Equity Act is important*
16 *legislation that will raise awareness that, because children and*
17 *adults react to drugs in different ways, trying to calculate dosages*
18 *on the basis of what is appropriate for adults risks over- and under-*
19 *medicating children; and*

20 *WHEREAS, According to the American Academy of Pediatrics,*
21 *only approximately 25 percent of all drugs on the market today*
22 *have been tested or labeled for safe and effective use in children;*
23 *and*

24 *WHEREAS, According to the FDA, pediatric testing has been*
25 *done on 91 medications, which is far less than the 400 drugs for*
26 *which the agency has requested studies in children; and*

27 *WHEREAS, As a result of the Pediatric Research Equity Act,*
28 *increased testing and research on drugs prescribed for children*
29 *will help guide sound treatment planning, increase access to more*
30 *effective treatment options for children and adolescents living with*
31 *physical and mental illnesses, and destigmatize child and*
32 *adolescent mental illnesses; and*

33 *WHEREAS, Children are a unique population with special*
34 *medical needs and access to drugs that have been properly tested*
35 *for pediatric use will ensure that they are safe and will work to ease*
36 *children's pain and suffering or make them healthy; now, therefore,*
37 *be it*

38 *Resolved by the Assembly and Senate of the State of California,*
39 *jointly, That the Legislature of the State of California commends*
40 *the Congress and the President of the United States for enacting*

1 *the landmark Pediatric Research Equity Act of 2003 and thereby*
2 *recognizing the importance of testing the safety and effectiveness*
3 *of drugs for pediatric use, a victory for children's health and*
4 *well-being; and be it further*

5 *Resolved, That the Chief Clerk of the Assembly transmit copies*
6 *of this resolution to the President and Vice President of the United*
7 *States, to the Commissioner of the Food and Drug Administration,*
8 *to the Secretary of Health and Human Services, and to each*
9 *Senator and Representative from California in the Congress of the*
10 *United States.*

11 ~~States between six and 18 years of age are taking psychotropic~~
12 ~~drugs; and~~

13 ~~WHEREAS, There appears to be an increase in prescribing~~
14 ~~psychotropic drugs to youths younger than 20 years of age, with~~
15 ~~the number of children receiving psychotropic medication of all~~
16 ~~types increasing two to three-fold between 1987 and 1996,~~
17 ~~according to a January, 2003, study published in the Archives of~~
18 ~~Pediatrics and Adolescent Medicine; and~~

19 ~~WHEREAS, Recent national media attention has focused~~
20 ~~concern on the use and unknown long-term effects of stimulants~~
21 ~~like Ritalin, amphetamines like Dexedrine, and antidepressants~~
22 ~~like Paxil, Prozac, and Zoloft for children; and~~

23 ~~WHEREAS, There is increasing concern that side effects from~~
24 ~~stimulants, antidepressants, antipsychotics, mood stabilizing~~
25 ~~anticonvulsants and other psychotropic agents may cause children~~
26 ~~and adolescents to become intensely nervous, restless, anxious,~~
27 ~~and, possibly, more violent in school; and~~

28 ~~WHEREAS, Symptoms of childhood and adolescent mental~~
29 ~~disorders, such as generalized anxiety disorder, obsessive~~
30 ~~compulsive disorder, major depressive disorder, bipolar disorder,~~
31 ~~schizophrenia, attention-deficit hyperactivity disorder, and~~
32 ~~autism, include repeated feelings of intense internal or emotional~~
33 ~~anxiety, lasting depression, low self-esteem, inattentiveness,~~
34 ~~aggression, and difficulty learning or understanding the feelings~~
35 ~~of others, and it is not uncommon for children to have more than~~
36 ~~one of these disorders; and~~

37 ~~WHEREAS, There is general agreement that mental illnesses in~~
38 ~~youth cannot be diagnosed appropriately without consulting with~~
39 ~~a variety of professionals and clinicians; and~~



1 ~~WHEREAS, When prescribed appropriately by a psychiatrist,~~
2 ~~preferably a child and adolescent psychiatrist, and taken as~~
3 ~~prescribed, medication may reduce or eliminate symptoms and~~
4 ~~improve the daily functioning of children and adolescents~~
5 ~~diagnosed with psychiatric disorders; and~~

6 ~~WHEREAS, Most psychotropic drugs have not been approved~~
7 ~~by the federal Food and Drug Administration (FDA) for pediatric~~
8 ~~and adolescent use; and~~

9 ~~WHEREAS, Research is needed to determine the long-term~~
10 ~~safety of psychotropic medications in light of earlier ages of~~
11 ~~initiation and longer duration of treatment; and more long-term~~
12 ~~studies are needed to examine drug concentrations in body fluids~~
13 ~~and tissues over time in children and adolescents to determine the~~
14 ~~appropriate dosage for youth of different ages and body sizes; and~~

15 ~~WHEREAS, The lack of a body of long-term research on~~
16 ~~psychiatric medications for youth has resulted in widespread~~
17 ~~“off-label” use, meaning that physicians who prescribe a specific~~
18 ~~drug to children and adolescents do not have the benefit of research~~
19 ~~and drug-labeling information developed by the sponsor and~~
20 ~~approved by the federal Food and Drug Administration (FDA) for~~
21 ~~this specific population; and~~

22 ~~WHEREAS, It is important that children’s mental health needs~~
23 ~~be recognized, but that caution be exercised in suggesting~~
24 ~~treatment; now, therefore, be it~~

25 ~~*Resolved by the Assembly and Senate of the State of California,*~~
26 ~~*jointly, That the Legislature of the State of California respectfully*~~
27 ~~*memorializes the President and the Congress of the United States*~~
28 ~~*to urge the FDA to probe the reasons for the rise in the use of*~~
29 ~~*prescription psychotropic drugs to manage mental health*~~
30 ~~*problems in youth; and be it further*~~

31 ~~*Resolved, That the President and the Congress of the United*~~
32 ~~*States urge the FDA to develop expanded clinical trials,*~~
33 ~~*longitudinal studies, and other long-term research on the*~~
34 ~~*appropriate use of medication in the psychiatric treatment of*~~
35 ~~*children and adolescents; and be it further*~~

36 ~~*Resolved, That the Chief Clerk of the Assembly transmit copies*~~
37 ~~*of this resolution to the President and Vice President of the United*~~
38 ~~*States, to the Speaker of the House of Representatives, to the*~~
39 ~~*Majority Leader of the Senate, and to each Senator and*~~

1 ~~Representative from California in the Congress of the United~~
2 ~~States.~~

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